

### **REMARKS**

Favorable reconsideration is respectfully requested in view of the above amendments and the following remarks. Following the amendments, claims 1-3 and 5-20 are pending and under consideration, with claim 1 being in independent format.

Claim 1, part (f) has been amended to be in “means plus function” format. Specifically, claim 1 has been amended to recite a testing device comprising a signal processing means for determining whether liquid sample reaches the detection arrangement within a pre-determined time period, wherein detection of the presence of the liquid sample at the detection arrangement within the pre-determined time period produces a negative result and absence of the liquid sample at the detection arrangement within the pre-determined time period produces a positive result. Claim 20 has been amended to correspond to the language of amended claim 1. Support for these amendments may be found, for example, in paragraphs 0026 and 0045 of the published US application.

It is urged that support for all the above amendments may be found throughout the specification as originally filed and that none of the amendments constitute new matter or raise new issues for consideration.

Applicants believe that claim 1, part (f), as amended, fully satisfies the 3-prong analysis required to invoke 35 USC §112, sixth paragraph, as delineated in MPEP §2181. Specifically, claim 1, part (f) includes the phrase “means for”; the “means for” is modified by functional language (i.e. determining whether the liquid sample reaches the detection arrangement within a pre-determined time period); and claim 1 part (f) does not include sufficient structure for achieving this specified function. Applicants respectfully request that claim 1 part (f) be treated under 35 USC §112, sixth paragraph.

Applicants wish to thank the Examiner for the telephone interview with their representative on September 23, 2009.

**Claim rejections under 35 USC §103**

Claims 1-3, 9, 10 and 12-20 stand rejected under 35 USC §103(a) as being unpatentable over Allen et al. (US Patent 5,837,546). This rejection is respectfully traversed.

Allen et al. disclose a sample testing device for testing for the presence of a component of interest in a liquid sample that includes a porous reaction strip, sampling region, a power source, a detection arrangement, a display means and a signal processing means. The Examiner asserts that the signal processing means of Allen et al. includes a timer. However, Allen et al. do not teach or suggest a testing device including a means for determining whether or not a liquid sample reaches the detection arrangement within a pre-determined time period, as clearly recited in amended independent claim 1. It is this detection of the liquid sample at the detection arrangement within the pre-determined time period that leads to a negative result. A positive result is obtained when presence of the liquid sample at the detection arrangement is not detected with the pre-determined time period. The timer referred to in the Allen et al. reference is only used as a control, i.e. to determine whether the test has run correctly or to determine test accuracy (see col. 10, lines 1-16 and claim 6 of Allen et al.).

Furthermore, while as noted by the Examiner, Allen et al. state that their device as a whole can have “any convenient shape” (col. 7, lines 54-67), the Allen et al. device clearly employs a reagent strip and not a capillary tube as recited in independent claim 1.

Applicants submit that Allen et al. do not teach or suggest the subject matter recited in amended independent claim 1. Claims 2, 3, 9, 10 and 12-20 depend upon claim 1 and therefore necessarily include all the limitations of claim 1.

It is urged that the disclosure of Allen et al. would not have rendered the presently claimed invention obvious to one of skill in the art at the time the present application was filed, and that the rejection of claims 1-3, 9, 10 and 12-20 under 35 USC §103(a) as being unpatentable over Allen et al. can thus be properly withdrawn.

Claims 5-8 stand rejected under 35 USC §103(a) as being unpatentable over Allen et al. in view of Wilding et al. (US patent 5,486,335). This rejection is respectfully traversed.

The disclosure of Allen et al. is discussed above.

Wilding et al. disclose a device for detecting the presence of an analyte in a fluid sample. The Examiner asserts that Wilding et al. teaches the use of beads coated with a binding protein specific for a given analyte in a testing device. However, Wilding et al. do not overcome the deficiencies of Allen et al. discussed above.

It is submitted that neither Allen et al. nor Wilding et al., taken either singly or in combination, would have rendered the subject matter of claims 5-8 obvious to one of skill in the art at the time the invention was made, and that this rejection of claims 5-8 under 35 USC §103(a) can thus be properly withdrawn.

Claim 11 stands rejected under 35 USC §103(a) as being unpatentable over Allen et al. in view of Forrow et al. (US 6,764,581). This rejection is respectfully traversed.

The disclosure of Allen et al. is discussed above.

Forrow et al. disclose an electrode for use in an electrochemical sensor for measuring an analyte. The Examiner asserts that it would have been obvious for one of ordinary skill in the art "to modify the modified Allen's test capillary tube by specifically having his detection arrangement beneath an aperture in the downstream regions of the test capillary tube, as disclosed by Forrow". However, the teachings of Forrow et al. do not overcome the deficiencies of Allen et al. discussed above.

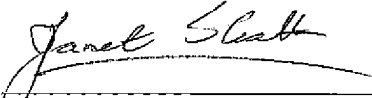
Applicants submit that neither Allen et al. nor Forrow et al., taken either singly or in combination, would have rendered the subject matter of claim 11 obvious to one of skill in the art at the time the invention was made, and that this rejection of claim 11 under 35 USC §103(a) can thus be properly withdrawn.

#### **Concluding Remarks**

A Request for a Two Month Extension of Time, extending the deadline for responding to the Office Action to October 20, 2009, is submitted herewith.

Early reconsideration and allowance of the pending claims is respectfully requested. Should the Examiner have any remaining concerns regarding the subject application, she is respectfully requested to telephone the undersigned at 206.382.1191.

Respectfully submitted,

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